

The Marshfield Clinic Personalized Medicine Research Project

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Personalized Medicine Research Project

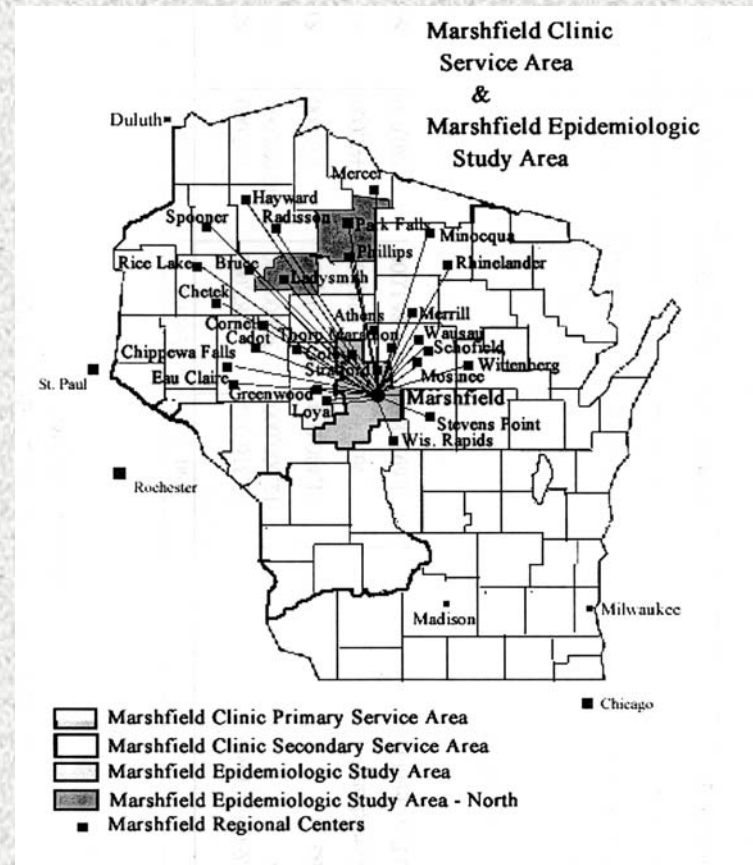
- Ultimate Goal:
 - Translate genetic data into specific knowledge about disease that is clinically relevant and will enhance patient care
- Short term Goal:
 - Establish database to allow research in genetic epidemiology, pharmacogenetics, population genetics

Personalized Medicine Research Project

- Phase I: Consultation and initial enrollment
- Phase II: Creating the infrastructure for a national resource and expanding the database
- Phase III: Genetic discovery projects, physician education and consultation

Why Marshfield?

- Marshfield Epidemiologic Study Area (MESA)
 - Well studied and documented population
 - Primarily MC patients
 - Many families have lived in MESA for many generations



Why Marshfield?

- Marshfield Clinic system of care
- Extensive Electronic Medical Record (CMR) for two decades
 - MECCA disease lexicon
- Research Foundation with strong programs in genomics and clinical research

Phase I Consultation

- Ethics and Security Advisory Board
- Scientific Advisory Board
- Community Advisory Group
- Focus group discussions

Ethics and Security Advisory Board

- Norman Fost, MD, MPH, Chair
 - Jeffrey Botkin, MD
 - Ellen Wright Clayton, MD, JD
 - Father J. Thomas Finucan, PhD
 - Michael Kaback, MD
 - Jon Merz, JD, PhD
 - Geraldine M. McQuillan, PhD
 - Professor Karen Rothenberg, JD
 - Bishop April Ulring Larson
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Scientific Advisory Board

- David Altshuler, MD, PhD; Chair
- David A. Flockhart, MD, PhD
- Stephen B. Liggett, MD
- Gabor T. Marth, D.SC
- Jurg Ott, PhD
- Leena Peltonen, MD, PhD
- Wendell W. Weber, MD, PhD

Community Advisory Group

- 16 members from government, media, local business and general community members representing most communities

Community Consultation and Awareness Activities

- Focus group discussions
- Talks to community groups
- Press releases and print interviews
- Inserts in local newspapers
- Posters in Clinic and throughout communities
- Radio interviews



RESEARCH HAS LONG BEEN THE BASIS FOR IMPROVING MEDICINE AND HEALTH CARE

- In as little as 30 minutes, you can contribute to medical research.
- You will be compensated \$20 for your time.
- Over 14,000 central Wisconsin residents have already enrolled.

WHAT IF, IN THE FUTURE, YOUR DOCTOR COULD:

- prevent or detect which illnesses you or your family have or are likely to get and design a personalized health care plan to diagnose and treat early
- diagnose diseases accurately and use medications and other treatments that would work best for each individual
- treat appropriately, avoiding medications that would cause you to have bad side effects

If you are 18 or over and living in one of these 19 ZIP codes, you are eligible.

54405	54420	54437	54454	54484
54410	54421	54441	54466	54488
54412	54425	54446	54771	54489
54415	54436	54449	54479	

If you would like to learn more about Marshfield Clinic's Personalized Medicine Research Project, what it is and is not, and how to participate, ask your health care provider or call **715-389-7733** or toll free at **1-866-334-2232** to talk with one of our research coordinators. Appointments are not necessary. Walk-ins are welcome.



Back row: Jim Churchill, Bob Wahl
Front row: Larry Wahl, Jerry Mize, Paula Hensel

"When I found out about the personalized medicine program, I saw the project as a good thing for the future. If participating benefits someone down the line, we should be doing these things. It goes hand in hand with what we do here at the Pittsville Fire Department. We help people. There is some personal satisfaction in helping people."

Joe Gled Jerry Mize



MARSHFIELD CLINIC.

Where the future of medicine lives

Study Logistics

- Recruitment commenced September 2002
 - MESA residents aged 18+ contacted by letter and telephone (600-1000 letters per week)
 - Saturday and evening times, regional centers
 - Spanish interpreter
 - 30-90 participants per day (30 minute appts)
 - Written informed consent and questionnaire
 - Consenting participants donated blood for DNA extraction, storage of plasma and serum
 - \$20 reimbursement for expenses (10% return)
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Questionnaire

- Race and ethnicity (US census questions and categories)
 - Occupation and industry
 - Adverse drug reactions
 - Smoking, alcohol use
 - Family history of heart attack, lung cancer, colon cancer, breast cancer, diabetes, epilepsy, and other conditions
 - First degree relatives in study area
 - Height and weight measured
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Security Provisions

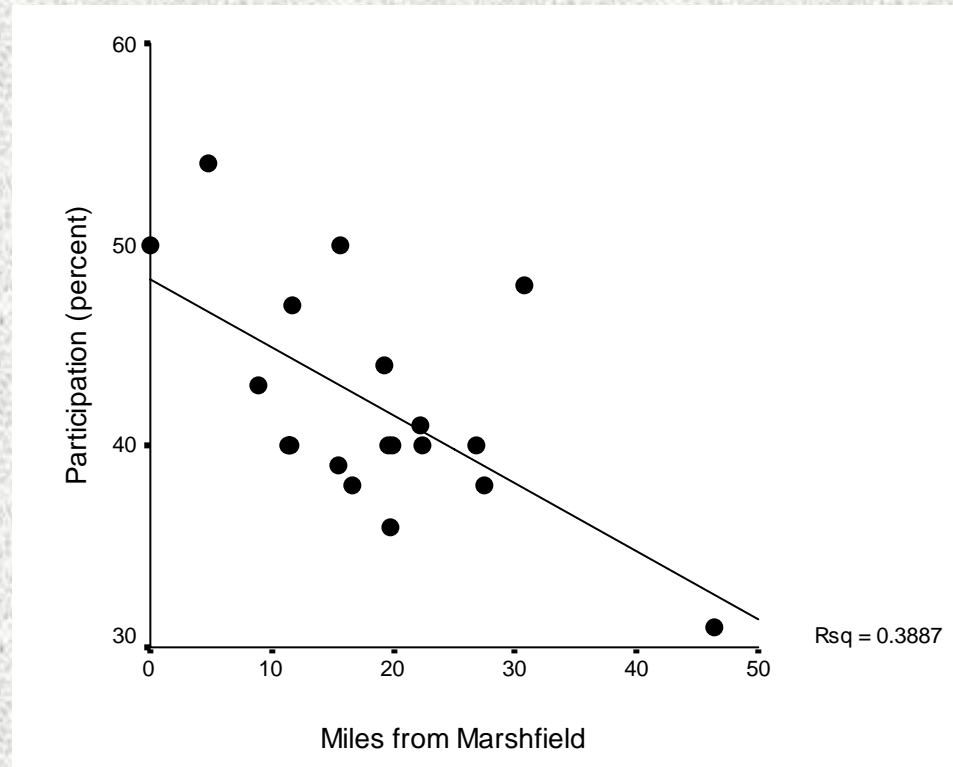
- Certificate of Confidentiality obtained
 - Encryption
 - Security (physical and non-physical)
 - No one with access to identifiable medical information will also have access to genetic information
- Marshfield Clinic Policy on Privacy (relating to genetic research)
- Wisconsin laws

Percent 'Yes' Response

Overall= 45%, n=17739

- Hewitt, 54%, 250
- Pittsville, 48%, 884
- Spencer, 43%, 1066
- Milladore, 44%, 315
- Blenker, 50%, 16
- Chili, 40%, 269
- Colby, 40%, 689
- Stratford, 40%, 1192
- Abbotsford, 41%, 640
- Marshfield, 50%, 8178
- Auburndale, 47%, 630
- Unity, 39%, 255

Relation of participation rate to distance from Marshfield



Reasons for Non-Participation

- Not interested, 71.3%
- Inconvenience, 16.4%
- Other, 5.7%
- Blood draw, 2.4%
- Privacy, 2.1%
- Oppose genetic testing, 1.1%
- Religious, 0.04%

Participant/Non-Participant Comparison

Variable	Participants	Non-Participants
Mean age in yrs (SD)	48.9 (17.9)	49.2 (18.6)
Percent female	57.2%	49.3%
Number of unique diagnoses in 2002	14.3 (11.3)	12.2 (11.2)
Mean diagnosis records in 2002	34.4 (44.1)	30.4 (46.1)

Participant Demographics, n=17,463

- Race
 - Caucasian, 98.4%
 - American Indian, 0.8%
 - Hispanic, 1.0%
 - Asian, 0.4%
 - Other, 0.2%
 - African American, 0.2%
- Ethnicity
 - German, 76.7%
 - Irish, 16.5%
 - English, 16.1%
 - Other, 15.5%
 - Polish, 12.3%
 - Norwegian, 11.7%
 - French, 9.6%
 - Swedish, 6.5%
 - Dutch, 6.1%
 - Czech, 3.7%

Participant Residence

- Current
 - Working farm, 8.3%
 - Rural home or hobby farm, 30.7%
 - Suburb, city, village, 60.9%
 - Other, 0.6%
- Ever lived on a working farm, 53.9%

Participant Exposure Status

- Smoking status:
 - Current, 18%
 - Past, 28%
 - Never, 54%
- Personal and/or family history of adverse drug reactions, 15.0%

Opt-out on Consent form

- 142/117,463 (0.8%) participants ask to not be contacted for future studies

Current/Planned Projects

- Phenotyping pilot projects
- Breast cancer in farm women
- Alzheimer's Disease
- Family history/pedigree development
- Obesity
- Pharmacogenetics
- ELSI research
- Congestive heart failure
- Research collaborations – IP, etc

Investigators

- Principal Investigators
 - Michael Caldwell MD PhD
 - Catherine McCarty PhD

- Co-Investigators
 - James Burmester PhD
 - Donna Chapman-Stone
 - Nader Ghebranious, PhD
 - Robert Greenlee PhD
 - Peggy Peissig
 - Stephen Wesbrook PhD
 - Robert Carlson MD
 - Carl Christensen
 - Philip Giampietro MD PhD
 - Dan McCarty PhD
 - Kurt Reed MD
 - Russell Wilke MD PhD

Funding

- Office of Rural Health Policy, Health Resources and Services Administration
1 D1A RH00025-01
 - Technology Development Fund Program, Department of Commerce, State of Wisconsin
 - Marshfield Clinic
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- Approximately \$150 per person to enroll